

REMARKS

Claims 72-90 are pending in the present application and at issue.

The section of the specification entitled "Cross-Reference to Related Applications" has been amended to refer to all of the prior related applications.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 72-90 under 35 U.S.C. 103

Claims 72-90 are rejected under 35 U.S.C. 103 as being unpatentable over Lischnig et al. (Biotechnology Letters, Vol. 15, No. 4, pp. 411-414 (1993)) or Gomes et al. (Appl. Microbiol. Biotechnol., Vol. 39, pp. 700-707 (1993)) or Alam et al. (Enzyme Microb. Technol., Vol. 16, pp. 298-302 (1994)) and Haarasilta et al. (U.S. Patent No. 5,314,692) and Hazlewood et al. (WO 93/25693). This rejection is respectfully traversed.

Lischnig et al. disclose an endo-beta-xylanase derived from *Thermomyces lanuginosa*, DSM 5026, which has a pH optimum of 6.5 and is active at pH values up to 9.0, and has a residual activity of at least about 80% after incubation at 70°C for 10 minutes at pH 6-9. Lischnig et al. also disclose that the xylanase shows sufficient thermostability for use as a bleaching aid in the pulp and paper industry.

Gomes et al. disclose a xylanase derived from a *Thermomyces lanuginosa* strain, which was deposited at Deutsche Sammlung von Mikroorganismen und Zellkulturen under the number DSM 5826. Gomes et al. further disclose that the xylanase was almost thermostable (91-92%) at pH 6.6 and 9.0 after 41 hours preincubation at 55°C and lost only 20-33% activity after 188 hours. Gomes et al. further disclose that the xylanase is extremely valuable in the bleaching of paper pulp.

However, neither Lischnig et al. nor Gomes et al. disclose animal feed compositions comprising a thermostable xylanase of Family 11, as claimed herein.

Alam et al. disclose thermostable xylanases derived from *Thermomyces lanuginosus* and *Thermoascus aurantiacus*. These xylanases are disclosed as holding a great potential for application in pulp, paper, and jute fiber processing industries. In the summary of Alam et al. (lines 3-4) it is further disclosed that *T. lanuginosus* produced cellulase-free xylanase, and *T. aurantiacus* produced only a small amount of cellulase in addition to xylanase. Alam et al. do not in any way whatsoever teach or suggest the use of the disclosed *Thermomyces* xylanases in

animal feed applications. The only disclosure relating to animal feed in Alam et al. is in the introduction where Alam et al. state that in some cases, there is a synergistic effect between xylanases (in general) and cellulase, e.g. maximum conversion of lignocellulose into liquid feedstocks and increasing the digestibility of animal feed. However, this statement clearly does not apply to the *Thermomyces* xylanases since they are either cellulase-free or have only a small amount of cellulase, and furthermore the only disclosure of utilities of the *Thermomyces* xylanases in Alam et al. is biopulping and jute fiber processing (see page 301, left hand column, last paragraph). Thus, Alam et al. do not disclose the use of *Thermomyces* xylanases in animal feed applications.

Significantly, none of the cited references teach or suggest the use of thermostable xylanases in animal feed compositions, or that there would be any advantage to using a thermostable xylanase over a thermolabile xylanase in animal feed.

Moreover, Applicants have demonstrated that the use of thermostable xylanases of Family 11 according to the present invention significantly improves feed utilization as compared to other xylanases. For example, Example 6 at pages 37-38 of the specification demonstrates that, surprisingly, a *Thermomyces lanuginosus* xylanase of the present invention has significantly improved properties in reducing wheat viscosity in vitro than a prior art xylanase (a commercially available multicomponent enzyme preparation derived from *Humicola insolens*). See also Figure 4, which shows a much higher efficiency of the xylanase of the invention as compared to the prior art xylanase per unit dosage with respect to viscosity reduction. Using for example 1.29 activity units per gram of wheat of each of these xylanases, the relative viscosity when using the xylanase of the invention is about 40%, whereas it is only about 75% when the prior art xylanase is used. As described in the example, there is a close correlation between reduction of viscosity and improvements in chicken feed conversion efficiency.

In addition, Example 7 (in particular Table 2) shows that, surprisingly, a *Thermomyces lanuginosus* xylanase of the present invention has a significantly improved feed conversion ratio when dosed at 200 and 400 FXU/kg feed than a prior art xylanase preparation even when dosed at the higher dosages of 400 and 800 FXU/kg. Example 7 concludes at page 41, lines 10-11, that the xylanase of the invention surprisingly is 4 times more effective than the prior art xylanase, when used at the same dosage of xylanase activity units.

Furthermore, in Example 8, Applicants have compared the digestibility of animal feeds comprising a thermostable xylanase of Family 11 ("A" and "B") vs. the digestibility of an animal feed comprising Bio-Feed Plus ("C"), a commercially-available xylanase preparation derived from

Humicola insolens. The results show that the use of Bio-Feed Plus at a dose of 400 FXU/kg gave a % fat digestion of 72.4, whereas the animal feeds comprising a xylanase of the present invention gave a % fat digestion in the range of 72.1-74.3 even though the xylanase was dosed at 100 or 200 FXU/kg (one quarter or one-half, respectively, of the Bio-Feed Plus). These results demonstrate that animal feeds comprising a thermostable xylanase of Family 11 have a significantly better digestibility than an animal feed comprising Bio-Feed Plus. Since the demonstrated superior property is not predicted by the prior art, these results are surprising and unexpected and the showing overcomes any assertion of obviousness based on the cited art.

In the Office Action, the Office alleges that these results are not surprising and unexpected because "it is possible that the enzyme concentration of 400 FXU/kg may be a saturating concentration such that increased amounts of the enzyme had no effect on the % fat digestibility." This is respectfully traversed.

The same xylanase is used in Examples 6-8. The results of Example 7 (shown in Table 2) show that the xylanase performs better when dosed at 800 FXU/kg. Accordingly, 400 FXU/kg is not a saturating concentration. Furthermore, the results of Example 6 (shown in Figure 4) show that a dosage of 400 FXU/kg (corresponding to 0.4 FXU/g) is not a saturating concentration.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

II. The Rejection of Claims 54-70 under the Doctrine of Obviousness-Type Double Patenting

Claims 54-70 are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,245,546.

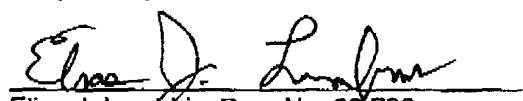
Applicants will submit a terminal disclaimer upon an indication of allowable subject matter.

III. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: May 26, 2004



Elias J. Lampris, Reg. No. 33,728
Novozymes North America, Inc.
500 Fifth Avenue, Suite 1600
New York, NY 10110
(212) 840-0097